

SPL Process ER/DL Meeting

Meeting Minutes

Aug 27, 2014

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. Reminder – September 1, 2014 - Implementation of “Combination Product Type” data element for CDER-regulated products

Donna Alvarez: Regarding the implementation of the “Combination Product Type” data element for CDER-regulated products, my colleagues have the following questions:

- How do we determine the SPL acceptable Term for RB's OTC Drug/Device combination products (for example, would be select type 9 for a liquid suspension with a dosing device)?

Lonnie is not ready to talk about categories yet. He will get back to us on any specific questions.

Approved drugs: Contact the review division to determine what category should be used.

OTC:

- Combination product web site:
<http://www.fda.gov/combinationproducts/aboutcombinationproducts/ucm101496.htm>
- For Definitions of the Combination product categories, go to the SPL Resources page – terminology files
- <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

SPL Terminology Files for Validation

- Active Ingredient-Active Moiety Relationship/Basis of Strength marketing category.)
- Additional Validation Files (XML)
- Combination Product Category Types (XML and Excel)
- Cosmetic Product Category Codes

- How does this impact the current listings? Do we need to update them all by the end of December or can we update them as we make updates to the products?

Response: No need to update all SPLs by December. Add this at your next normal update to the SPL for drug listing.

- Should we anticipate any import issues with our current listings (that haven't been updated yet)?

Response: Added for the combination product reviewers. Import people probably are not looking at this data element. Therefore this shouldn't be looking at this element.
Ask Paul/Vada about this.

- Does the Device part (Dosing cup) of Drug/Device combination require any identifier (e.g. component code, design code etc.)? (The form we received from our vendor only asks us to select the appropriate combination product type.)

SPL combination data element, does not require this data.

Pat has a question about the Combination Type categories too.

- Is a combination drug/device (syringe) that is approved through CDER, but has a BLA – considered a drug (Type 2) or biologic (Type 3) ?

If is a BLA, then it is considered a biologic product.

Combination Product Types

Source: National Cancer Institute Thesaurus

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

| SPL Acceptable Term | Code |
|--|---------|
| Type 0: Not a Combination Product | C112160 |
| Type 1: Convenience Kit of Co-Package | C102834 |
| Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.) | C102835 |
| Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.) | C102836 |
| Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | C102837 |
| Type 5: Device Coated or Otherwise Combined with Biologic | C102838 |
| Type 6: Drug/Biologic Combination | C102839 |
| Type 7: Separate Products Requiring Cross Labeling | C102840 |
| Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type) | C102841 |
| Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product) | C102842 |

2. Open FDA -- the API data base, <https://open.fda.gov/update/drug-product-labeling/>, (Herb O'Brien) SPL Leads do not know anything about this topic. From looking at the web site, Open FDA seems to be a way for IT type folks to access FDA's public databases -- ie a way give downstream users a way to download public information. One of the sources of data/information is our beloved SPL. We invite open discussion from anyone who may know something about this.
 - a. What is it? Who uses it?
 - b. How does it works with or impacts SPL.

Lonnie Smith attended the meeting to give a brief overview:

Open FDA will makes downstream use of SPL easier! API -- in this case -- is 'Application Program(ming) Interface'. Open FDA is aimed at techie people looking to capitalize on FDA data sources.

It is important to note that at the very top of the web page are the following statements: "**We're in beta!** openFDA is a beta research project and not for clinical use." At this time, this is a research project.

There is an OpenFDA e-mail address which was set up specifically to answer questions regarding OpenFDA. Also, most of your questions are answered on the web page accessible via the hyperlink. Here is a just one snippet from the web page which seems to some of the answers:

“Although it has been publicly available for many years on FDA’s website, now this labeling is available on [openFDA](#) through an Application Programming Interface (API), which provides a way for software to interact directly with the data.

“For several years, the labeling have been posted publicly in Structured Product Labeling (SPL) format at <http://labels.fda.gov/>. The SPL format enhances the ability to electronically access, search, and sort information in the labeling. The SPL files are also available at the National Library of Medicine’s DailyMed site and can be downloaded. We’ve created an API for the data to supplement (not replace) these resources, and to provide easy and timely access to changes or updates to the labeling.”

Targeted users: OpenFDA will make FDA data more available – primarily to software developers rather than to individual consumers. Normal users will typically access this data by using an app (eg Daily Med, FDA label system) and potentially to other apps (iphone apps, etc) without having to download all 65,000 SPL file.

Also, for years, the same SPL data has been accessed via DailyMed APIs: <http://dailymed.nlm.nih.gov/dailymed/help.cfm#webservices>.

Note: Recently, DailyMed staff added a few new APIs that they would like for software developers to review.

Public Service announcement from Terry: If you get questions about SPL on the techie side, pass along this link. FDA is providing this for free. Your folks won’t have to do this from scratch.

3. NDCs and and packaging sizes (Cora Colvin)

We are working on getting our new Pedigree/track and trace system in place and we noticed that some of our vendors have added an NDC “level” for the case quantity. We only create an NDC for the saleable unit sizes, we do not add the case quantity to our NDCs for an item. We wanted to get feedback to determine what is the best practice. Any feedback on this topic would be helpful!

Does anyone use case quantity – one distributor sells to another distributor...not sold to the consumer.

Finished product

- Intended for ultimate customers

API, bulk, or in process:

- Used larger quantities of cases related to shipping quantities.

4. Business operations for “filling” sites: (Ken Stevenson)

My client is the labeler and receives bulk finished product from their manufacture. After the receipt of the bulk, my client then fills the product in final packaging and affixes their artwork. This is performed at the client’s site. For the labeler who is “filling”:

- What is the correct business operation(s) to include in the establishment registration?
- What info should be included in the final product listing under the labelers label code? ie header and data elements of XML

The info I received from CDER addresses the labeler and states:

- In this scenario, the labeler is a manufacturer, therefore must register and list with FDA. It should be identified as "Manufacture, Pack and Label" on the SPL. The drug it manufactures and distributes, must be listed under the appropriate Marketing Category (i.e., NDA, ANDA, Unapproved Drug Other), under its own labeler code and NDC.
- GDUFA listing is manufacturer.
- SPL business operation is pack and label.

I would also like to ask what the listing requirements are for the manufacturer of the drums that are shipped to the labeler. Is this a bulk ingredient, etc?

- We handle this as a marketing category -bulk for further processing – always put a statement on the label that this is in process,

5. NDC questions (Mary Beth Kline)

Wondering how you would handle the following:

- If an NDC code is discontinued (removed from DailyMed), can the NDC number be reused if that same package size is brought back into the market?
- If a manufacturer changes, besides updating DailyMed, do we need to assign a new NDC since the packaging with the old manufacturer could be on the market (until it reaches expiry) at the same time the packaging with the new manufacturer is on the market?

Can you reuse the NDC code:

Two scenarios – using the NDC for the same product OR using this for a different product (covered by 21 CFR 207.25)

Same product: NDC can be reused – per 21 CFR §207.30 Updating drug listing information.

(3) A list of each drug for which a notice of discontinuance was submitted under paragraph (a)(2) of this section and for which commercial distribution has been resumed, including for each drug so listed the NDC number, the identity by established name and by proprietary name, the date of resumption, and any other information required by §207.25(b) not previously submitted.

Different product -- Based on 21 CFR 207.35

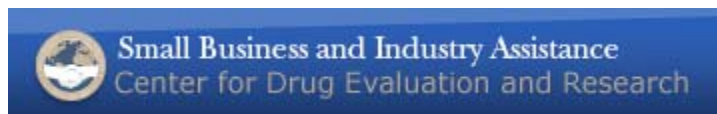
When a registrant has discontinued a drug product, its product code may be reassigned to another drug product 5 years after the expiration date of the discontinued product, or, if there is no expiration date, 5 years after the last shipment of the discontinued product into commercial distribution. Reuse of product codes may occur, under the specified conditions, regardless of the NDC, Product Code, and Package Code configuration used.

Different manufacturer – the NDC is based on the drug product....not the manufacturer.

The NDC relates to the product, not the manufacturer. Don't need a new NDC.

You can put both cartons in the SPL for the life of all material. But you don't need to. Some people use only the new carton. This is just like labeling.

6. On CDER new today, there was a link to a new web based training course on - "[Human Drug Establishment Registration and Drug Listing Compliance](http://www.accessdata.fda.gov/cder/sb-drls/index.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery)". Seems to get sponsored by Small Business and Industry Alliance



http://www.accessdata.fda.gov/cder/sb-drls/index.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

- Haven't watched it yet.

7. AOB

8. REMINDERS:

- SPL Jamboree 2014: National Library of Medicine has announced the 2014 SPL/DailyMed Jamboree Workshop which is scheduled for September 18, 2014, at NLM in Bethesda, MD. More information (including the agenda) regarding this free public SPL workshop is posted on this NLM web page: http://www.nlm.nih.gov/mesh/spl_workshop_2014.html.

Any plans for networking event the night before the Jamboree

- Craig Trautman is in charge of this. Stay tuned.

Hotels:

- Bethesda Court (Limited number of rooms): Normally \$229/night. They would hold 10 rooms for \$209/night and after the 10 rooms it would be \$219/night, if there are rooms left. This includes breakfast & wifi and is 2 blocks from Bethesda metro and is 1 1/2 miles from NIH campus. Ask for: NLM DailyMed Jamboree
- Marriot Pooks Hill - holding 15 rooms for \$189. They have a shuttle, but are a mile & 1/2 from a metro and 3 miles from NIH campus. Not as good for pre meeting options. Ask for: NLM DailyMed Jamboree

Both hotels would hold room rates until Sept 5th.

- Sept 1, 2014 – Implementation of "Combination Product Type" data element for CDER-regulated products